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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. |
|-----------------|-------------|----------------------|---------------------|
| 08/757,904 | 11/27/96 | WEGMAN | E WEG-2 |

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18M2/0401

EXAMINER

WITZ, J

ART UNIT

PAPER NUMBER

1808

DATE MAILED: 04/01/97

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.
08/757,904

Applicant(s)
Wegman et al.

Examiner
Jean C. Witz

Group Art Unit
1808



☒ Responsive to communication(s) filed on Nov 27, 1996

☐ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

☒ Claim(s) 1-20 is/are pending in the application.

Of the above, claim(s) _____ is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) 1-20 is/are rejected.

☐ Claim(s) _____ is/are objected to.

☐ Claims _____ are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been
☐ received.

☐ received in Application No. (Series Code/Serial Number) _____.

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☐ Notice of References Cited, PTO-892

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

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DETAILED ACTION

Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. § 103 which forms the basis for all obviousness rejections set forth in this Office action:

A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Subject matter developed by another person, which qualifies as prior art only under subsection (f) or (g) of section 102 of this title, shall not preclude patentability under this section where the subject matter and the claimed invention were, at the time the invention was made, owned by the same person or subject to an obligation of assignment to the same person.

2. Claims 1-20 are rejected under 35 U.S.C. § 103 as being unpatentable over Lee et al. combined with Guidicelli et al.

Claims 1-19 are drawn to the reduction of adipose tissue at selected sites in the body comprising the introduction of collagenase and another proteinase into said tissue. Claim 20 is drawn to a method of reducing adipose tissue for cosmetic purposes.

Lee et al. teaches that collagenase plus chymopapain digests connective tissue. Adipose tissue is particularly disclosed as being effectively digested so as to obtain endothelial cells present therein. Guidicelli et al. discloses that it is conventional to use collagenase and trypsin for the purpose of digesting and isolating adipocytes.

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The disclosure of the Lee et al. patent is drawn to proteolytic enzyme composition containing collagenase "useful for hydrolyzing connective tissue in biological systems." See col. 3, lines 60-65. Further, at col. 5, lines 20-33, the patent states that "the teachings of the present invention [are] widely applicable in a number of tissue digestion procedures including those which involve in vivo digestion" While it is clear that the in vivo digestion of adipose tissue was not expressly disclosed, the teaching of a U.S. patent is not limited to its preferred embodiments. The prior art shows that connective tissue, including adipose tissue, may be digested by use of a collagenase-containing proteolytic composition and that such composition is conventionally administered in vivo for the exact purpose of dissolving a broad range of different types of connective tissue. It is noted that the Lee et al. reference discloses the effects of the claimed composition both in vitro and for in vivo application for the digestion of connective tissue wherever desired and as the claims call only for the reduction of adipose tissue, it would have been obvious and predictable to one of ordinary skill in the art to use conventional enzymes known to digest said tissue, regardless of its site the expected digestion, i.e. dissociating the cells of the tissue. The term "tissue" is defined as "an aggregation of morphologically and functionally similar cells" and "cellular matter regarded as a collective entity." As a result of disaggregation of these cells by dissolution of the connective tissue matrix, the tissue has been digested and therefore its amount has been reduced. Such is clearly taught as predictable from the teaching of Lee et al. such that one of ordinary skill in the art would expect that, should he/she wish to reduce the amount of any connective tissue, including adipose tissue, at a site in the body, one would be

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motivated to use a composition well known to digest said tissue with a reasonable expectation of success. It is noted that absolute predictability is not required under the standard of obviousness of 35 USC 103; all that is required is a reasonable expectation of success. In re Long, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985). Finally, with regard to claim language drawn to “for cosmetic purposes”, such language fails to patentably distinguish the claims over the disclosure of Lee et al. These cosmetic purposes include such a wide range of applications such as treatment of fatty cysts such that one of ordinary skill in the art would be motivated as disclosed and taught in the patent to digest the connective tissue, i.e. adipose tissue, contained therein with a reasonable expectation of success of said digestion, thereby reducing the adipose tissue at said site. Optimization of dose is well within the skill of the practitioner as the enzyme kinetics of collagenase and other enzymes based upon amount of substrate are well known.

3. This case is a file wrapper continuation and all art cited in the parent case has been incorporated into the instant case. Therefore, no Form 892, Notice of References Cited by the Examiner, has been included with this Office Action.

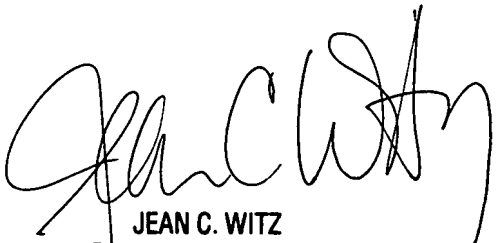
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4. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jean C. Witz whose telephone number is (703) 308-3073.

March 26, 1997



JEAN C. WITZ
PRIMARY EXAMINER
GROUP 1800